



ISO 9001:2008 REGISTRATION

The Medical Maintenance Operations Division of the Medical Maintenance Management Directorate, U. S. Army Medical Materiel Agency (USAMMA) was recently re-assessed and certified as meeting the new requirements of ISO 9001: 2008.

The term "ISO" is derived from the Greek word "isos", meaning equal. ISO standards are developed and administered by the International Standards Organization, an international organization to which approximately one hundred countries belong. The US representative is the American National Standards Institute.

ISO 9001 is not another fad quality system initiative. ISO is a permanent way of doing business, and doing business the right way, ensuring consistency in quality of products and services. The national standard applies to any organization and it specifies elements necessary for the foundation of a quality system. The national standard does not specify how the requirements are to be implemented and they do not replace product safety, or regulatory requirements. The general purpose of ISO is to provide standards for the development, implementation and management of a quality management system.

ISO 9001 registration is best viewed as a management tool that reaches far beyond the realm of "quality control" in a manufacturing environment, the application that first comes to mind to many people. Indeed, the FDA has already harmonized its Quality System regulation with ISO 9001, and even JCAHO has decided to integrate ISO 9001 into its own standards for healthcare organizations. For ISO 9001 purposes, the term "quality" is viewed as being synonymous with "excellence" and as applying to all segments of a company's operations, even those administrative functions that are sometimes not viewed as being part of the overall goals of the company in meeting its customers needs. For us, ISO 9001 has been a great management tool to promote excellence throughout all functions of our maintenance divisions.

The Medical Maintenance Operations Division has provided depot level maintenance for medical equipment for many years, and while we have established excellence and consistently provided high quality service during that time, implementing the ISO 9001 process has caused us to do even better. The ISO process, however, does not end with the initial certification; the ongoing requirement for continual improvement and surveillance audits ensures that our maintenance divisions will continue to maintain a world-class level of excellence.

We have seen significant payoffs in enhanced internal communications, increased efficiency and productivity, boosted unit moral and customer satisfaction. Much of this was accomplished through better documentation of policies and

processes with every individual having a clear vision of the objectives and ownership for part of the process. Obtaining ISO 9001 registration was not easy and required a significant commitment in terms of time and effort, but it has definitely been worth the effort, it has already paid for itself many times over.